PRIMARY MODE OF ACTION ASSIGNMENT ALGORITHM

Identify the combination product's modes of action:

- Drug and Device
- Drug and Biological Product
- Device and Biological Product
- Drug, Device and Biological Product

Which mode of action is the most important therapeutic action of the combination product?

DEVICE

STOP
Device Primary Mode of Action. Assign to agency component with responsibility for that type of device.

DRUG

STOP
Drug Primary Mode of Action. Assign to agency component with responsibility for that type of drug.

BIOLOGICAL PRODUCT

STOP
Biological Product Primary Mode of Action. Assign to agency component with responsibility for that type of biological product.

UNABLE TO DETERMINE WITH REASONABLE CERTAINTY

Is there an agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole?

YES

STOP
Assign to the agency component with responsibility for regulating other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole.

NO

Which agency component has the most expertise related to the most significant safety and effectiveness questions presented by the combination product?

STOP
Assign to the agency component that has the most expertise related to the most significant safety and effectiveness questions presented by the combination product.